



NHS Quality Improvement Scotland

Report of the Steering Group on the Safe, Effective and Efficient Use of Blood Components and their Alternatives

July 2004

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Executive Summary

Over 3 million units of blood component are used in the UK each year – 300,000 of these in Scotland. Blood is given in emergency situations, regularly and routinely for chronic disorders and before and after surgery and the service is dependent on freely given donations. Scotland is unique in that blood supplies exceed demand and over 250,000 donations are given each year. The Blood Transfusion service costs £65million each year (including Protein Fractionation services), or about £2 million for a large hospital each year.

The Scottish National Blood Transfusion Service (SNBTS) is responsible for collecting, processing, storing and supplying all blood components in Scotland and NHSScotland boards are responsible for ordering and managing their supplies in a safe and effective environment. Both SNBTS and NHSScotland are aware of the risks involved in all aspects of blood management and Scotland has invested in two important pieces of work:

- A Clinical Resource and Audit Group (CRAG) funded audit on the ‘Optimal Use of Donor Blood’; and
- An Audit Scotland study of hospital blood banks.

Both these pieces of work identified a number of areas where processes and practice could be improved and as a result of this, the Scottish Executive Health Department (SEHD) has introduced an extensive programme of work to improve and support transfusion practice (the Better Blood Transfusion Programme) and asked NHS Quality Improvement Scotland (NHS QIS) to consider how it could address the quality improvement issues identified in these reports.

NHS QIS set up a Steering Group to take this work forward and this document reports on the Group’s recommendations which focus on tackling key issues:

- **Standardising processes and practice across all aspects of blood management** with the aim of reducing wastage and identification errors, and improving tracking systems, in line with EU regulations that will come into force in 2005.
- **Reviewing transfusion protocols** with the aim of reducing the need for transfusion and improving pre-operative health status (for elective patients).
- **Stocktake of existing incident management systems, including reporting** with the aim of improving communication flows within the service and support learning from experience and the attendant reduction in errors.
- **Reviewing current options for cross matching and blood ordering** with the aim of speeding up the provision of blood while ensuring that blood resources are not ‘held’ unnecessarily and therefore unavailable to other patients.

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Blood Components and their Alternatives

The Group emphasised that communication with patients about risks and alternatives, training and support of staff and standard practice across all sectors, including the independent healthcare sector, is fundamental to achieving the aims stated above.

The recommendations made by the Group are given in full on page 13 of this report.

Acknowledgements

NHSScotland has a blood transfusion service to be proud of and this is also reflected in the high standards of practice in laboratory blood banks across Scotland. Thanks are due to the many people who have contributed to work that the NHS QIS Steering Group was able to draw on to inform this report, and in particular to:

- The Steering Group members (full membership list appears in Appendix 1)
- Dr Steve Engleman, Health Economist
- Mr Fraser Fergusson, Programme Director, Better Blood Transfusion Programme (BBTP), and the staff of BBTP
- Dr Aileen Keel, Deputy Chief Medical Officer, SEHD
- Ms Sandra Gray, Effective Use of Blood Manager, SNBTS

1. Introduction to NHS Quality Improvement Scotland

NHS Quality Improvement Scotland (NHS QIS) was set up by the Scottish Parliament in 2003 to take the lead in improving the quality of care and treatment delivered by NHSScotland. The responsibilities of NHS QIS cover all aspects of the services provided by the NHS and provide an independent check on how these services are performing. NHS QIS also supports NHS staff by issuing clear, authoritative advice on effective clinical practice and service improvements.

NHS QIS aims to support the delivery of:

- higher standards of care;
- improved outcomes for patients;
- better experiences for patients and carers; and
- better value for money.

Our objectives are achieved through four key functions that link together:

- providing advice and guidance on effective practice;
- setting standards;
- reviewing and monitoring performance; and
- supporting staff to improve services.

There are a variety of products provided by NHS QIS to improve the quality of care and treatment delivered at a national level. A list of these products is presented in Appendix 2.

This document is the summary of a scoping exercise conducted to determine how the use of blood components and their alternatives could be improved in NHSScotland. The purpose of the exercise was to make recommendations to the NHS QIS Board on how NHS QIS can best support services in improving the quality of care.

Further Information

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Copies of all NHS QIS publications and further information on the organisation can also be downloaded from the website (www.nhshealthquality.org).

2. Background and Context

The Scottish Executive Health Department (SEHD) ¹ has identified a need for improvement in the safe, effective and efficient use of blood components and their alternatives in NHSScotland. NHS QIS was tasked with eliciting expert advice from within NHSScotland to identify the key issues in transfusion services and recommend where NHS QIS could best support quality improvement within these services.

In 1995, CRAG established a multi-specialty working group that produced a report 'Optimal Use of Donor Blood', endorsed by CRAG and the CMO (*available on request from NHS QIS*). SNBTS also contributed to the development of the Serious Hazards of Transfusion (SHOT) Scheme², that collects analyses and reports on transfusion incidents in the UK and Ireland. The information gathered is used to inform policy, improve transfusion procedures and prepare clinical guidelines. MEL (1999)⁹³ requires that all NHS Boards participate in the SHOT scheme.

In 1999, Audit Scotland, at the request of SNBTS ⁴, carried out an audit of hospital blood banks ⁵. Variation in efficacy between banks, significant wastage of product and a lack of coherent information gathering across the service were identified as key areas of concern.

SNBTS, with funding from CRAG, initiated in February 2000, the study, 'Safe and Effective Transfusion in Scottish Hospitals – the Role of the Transfusion Nurse Specialist'⁶. The report of this work was submitted to NHS QIS in June 2004 and will be posted on the NHS QIS website shortly.

The Scottish Intercollegiate Guidelines Network (SIGN) has also issued a guideline (SIGN 54)⁷ covering perioperative blood transfusion for elective surgery. This aims to provide best practice recommendations to eliminate variation in standards of treatment across NHSScotland and so provide uniform care. The guideline recommends specific actions to minimise risks from transfusion and from surgery where major use of donor blood is required. Other recommendations include adopting measures to increase efficacy of blood ordering, strategies to improve patient management and minimising the number of transfusions undertaken. Although issued in 2001, many of the issues highlighted in the guideline still remain relevant. SIGN 54 is scheduled for review in November 2004.

Following on from this, HDL 2003/19⁸ established the Better Blood Transfusion Programme (BBTP)⁹. Initially a three year programme to enhance the quality of transfusion practice in Scotland, the BBTP promotes safety and best practice in efficient and effective blood management across NHSScotland, including the provision of training and education.

The UK Blood Services Joint Professional Advisory Committee (JPAC) is charged with providing professional guidelines for the UK Blood Services, published in print form and on the website www.transfusionguidelines.org.uk. JPAC also produces the UK Handbook of Transfusion Medicine¹⁰ a concise clinical guide that is largely based on guidelines developed by the British Committee for Standardisation in Haematology.

The Council of Europe¹¹ issues an annual guide on preparation, use and quality assurance of blood components that is widely used in Member States. An important consideration for the immediate future is EU Directive 2004/33¹² of the European Parliament¹³ and of the Council of 22 March 2004 (Implementing Directive 2002/98/EC of the European Parliament and of the Council as Regards Certain Technical Requirements for Blood and Blood Components). This directive comes into effect in February 2005 and is based on an earlier EU Directive, 2002/98/EC¹⁴ of the European Parliament and of the Council of 27 January 2003, setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC.

Member states are required to ensure that blood establishments implement a system for identification of each single blood donation, and each single blood unit and components, to enable full traceability to the donor as well as to the transfusion and the recipient.

An earlier Directive 2001/83/EC¹⁵ of the European Parliament and of the Council of 6 November 2001 on the Community Code (relating to medicinal products for human use) regulates the administration of medicinal products, including blood products and components.

3. Methodology

NHS QIS established a Steering Group in April 2004 to take this work forward. Membership of the Group included staff from SNBTS, a range of health professionals responsible for ordering, storing, and using blood components, members of the public and the independent healthcare sector (Appendix 1).

The Group's objectives were to:

- provide expert advice;
- inform the drafting of options and recommendations on the role of NHS QIS in supporting NHSScotland in:
 - the management of patients using and receiving blood components and their alternatives; and
 - the safe use of blood components and their alternatives; and
- scope NHSScotland activity generally with regard to the use of blood components and their alternatives.

The Steering Group held three meetings to address these objectives and used two pieces of work in particular as a foundation for discussion and to inform its recommendations:

- Hospital Blood Banks, Audit Scotland (1999)⁵.
- Safe and Effective transfusion in Scottish Hospitals - The Role of the Transfusion Nurse Specialist (SAET Study), SNBTS (14 April 2004)⁶.

The Group also worked in partnership with a range of other individuals and initiatives, in particular, the Better Blood Transfusion Programme, and received a number of informative presentations (Appendix 3). Throughout its work, the importance of identifying, and where possible meeting, patient needs and preferences was highlighted.

4. Feedback on Discussion Points

A wide range of topics and possibilities were discussed and considered and these were taken into account when preparing the recommendations made in section 5. These are summarised below and it should be noted that not all were considered appropriate for NHS QIS to take forward at this stage. It is recommended that NHS QIS regularly reviews this 'discussion checklist' in light of progress made in other related initiatives.

- 4.1 Development of **core standards**. It was recognised that measuring performance against standards that applied across every service area, in both acute and community settings, presented considerable challenges.
- 4.2 Ways of ensuring that transfusion and relevant risk management issues featured on the **Clinical Governance** Agenda, and that roles, responsibilities and reporting lines were clear.
- 4.3 Further exploration of the use of new technologies to improve **tracking** of blood from source to the recipient. Effective tracking to recipients will depend critically on the ability to issue patients with a unique patient identifier, eg Community Health Index (CHI) in a suitable secure machine readable form.
- 4.4 Effective capture and dissemination of **incident and near miss** data, linking up with the work already being undertaken by SHOT and the BBTP. Continued support should be provided for the training based on learning from incidents and experience and for the dissemination of this information.
- 4.5 Greater involvement of BBTP transfusion practitioners in **clinical and nursing training**. The BBTP has a training programme in place for all staff involved in transfusion practice and has completed training for approximately a thousand staff. The Group recognised the need to await the evaluation of the current three year programme.
- 4.6 Further exploration of a means of improving **networking** among transfusion practitioners to support training and the sharing of best practice.
- 4.7 Consideration of extending the availability of **preadmission clinics** for patients undergoing elective surgery likely to involve significant blood loss. Evaluate interventions to reduce transfusion needs by preoperative correction of anaemia and haemostasis problems. Where these clinics currently run, they are held around one week prior to surgery, and are very useful as they provide a timely opportunity to check that the patient is fit for surgery. Surgical pre-assessment at this time can also be useful in the provision of a sample for blood grouping and antibody screening; a group at this stage is particularly useful if electronic issue of blood is used; an antibody screen performed at this time is useful, in all cases, as it permits detection of possible irregular blood

group antibodies that otherwise could complicate the provision of compatible blood.

- 4.8 The evaluation of **patient held records** for patients needing regular transfusion or specialised blood products. This could reduce errors in blood administration and give patients control over an important aspect of their care.
- 4.9 In some hospitals, the use of conventional blood bank compatibility testing could be reduced, and more use be made of automated methods (so called “**electronic issue**”) for supplying compatible red cell units. This would help eliminate the need for an agreed number of blood units to be reserved for each type of surgical procedure and result in quicker supply from blood bank to patient.
- 4.10 Possibilities for **further clinical education** and training initiatives for all individuals involved in the process, including porters and laboratory technicians.
- 4.11 Standardisation of **terminology**.
- 4.12 Improved **information and data collection** systems, including accurate information on wastage of blood.
- 4.13 Research into the use and effectiveness of **alternatives to blood components**. These include the use of autologous blood, growth factors and coagulant/anticoagulant proteins. The impact of new technology such as blood salvaging techniques and near patient testing should also be assessed.

5. Recommendations

It was recommended that NHS QIS should explore in more detail the following for inclusion in the work programme:

5.1 Development and dissemination of standards for transfusion practice.

This would focus on areas where there are known to be deficiencies in current practice and would reinforce local quality improvement efforts.

5.2 Clinical and cost effectiveness advice (including HTA's and audit) on:

5.2.1 The use of electronic technology to facilitate the following:

- patient identification, particularly when taking samples for pre-transfusion testing;
- tracking red cells leaving the blood bank;
- checking the blood at the bedside immediately prior to transfusion;
- 'electronic issue' of blood.

5.2.2 Alternatives to transfusion such as the development of pre-admission clinics. Autologous transfusions (re-infusion of blood or blood products derived from the patient's own circulation) should also be considered.

5.2.3 The adoption of near patient testing as an alternative to laboratory testing services.

5.3 Clinical Governance and Patient Safety

5.3.1 Capturing, reporting and disseminating incident and near-miss data, including subsequent preventative training. This will first require wider development of the current incident reporting process and will involve close collaboration with SHOT.

5.3.2 Review of current risk management arrangements for blood components, including reporting lines.

5.3.3 Promoting learning from experience, including support for BBTP Practitioners and their work.

5.4 Best Practice Statements

5.4.1 Guidance on the identification of patient samples for cross-matching and on identification matching between patient and blood before transfusion.

6. References

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14. European Commission. Commission Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. www.dski.suite.dk/download/direktiv_engelsk.pdf url cited 15/06/04.
15. European Commission. Commission Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use. www.pharmacos.eudra.org/F2/pharmacos/docs/Doc2001/nov/Codifications/HumanCode2001-83/2001-83EN.pdf url cited 24/06/04.

The British Committee for Standards in Haematology (BCSH)
www.bcshguidelines.com also provide useful reference information.

7. Glossary

Term	Definition
Alternatives (to Blood Products)	Substitute procedures for transfusion. Covers administration of growth factors (e.g. erythropoietin) and coagulant and anticoagulant proteins.
Anticoagulant	A substance that prevents blood clotting.
Audit	Measurement of the quality and effectiveness of care.
Audit Scotland	Government body providing services to the Auditor General and the Accounts Commission of Scotland. Audit Scotland ensures that public money in Scotland is spent properly, effectively and efficiently by carrying out audits.
Autologous Blood	Blood taken from a patient which can then be reinfused. Autologous pre-donation involves the patient giving blood a few weeks prior to surgery; interoperative cell salvage involves the reinfusion of autologous blood during surgery.
Better Blood Transfusion Programme (BBTP)	NHSScotland programme set up to improve safety, efficacy and efficiency of transfusion practice.
BBTP Transfusion Practitioners	The role of the BBTP Transfusion Practitioner is to promote the safe, effective and efficient use of blood components and plasma derivatives by improving standards of care through establishing and co-coordinating education strategies, implementing and evaluating clinical practice developments and audit/research activities at the direction of the Better Blood Transfusion Programme Director/Hospital Lead Person.
Blood Components	A therapeutic constituent of blood (red cells, white cells, platelets, plasma) that can be prepared by various methods.

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Term	Definition
Blood Products	Any therapeutic product derived from human blood or plasma.
Blood Salvaging	Process where blood is recouped during surgery.
Blood Unit	A bag of whole blood collected from a donor and processed either for transfusion or further manufacturing.
British Committee for Standards in Haematology	Professional body which produces recommendations and guidelines on different haematology topics which are published at regular intervals.
CHI Number	Community Health Index Number; used to identify patients.
Chief Medical Officer	Principal medical advisor to the Scottish Executive and head of the Scottish Medical Civil Service.
Clinical Governance Agenda	A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.
Clinical Guidelines	Statements which provide recommendations on effective practice.
Clinical Resource and Audit Group (CRAG)	Former multi-disciplinary committee which provided advice to SEHD, acted as a national forum to support and facilitate the implementation of the clinical effectiveness agenda, and funded a number of clinical effectiveness programmes and projects. Now part of NHS QIS.
Coagulant	An agent that causes blood clot formation.

Term **Definition**

Council of Europe	International organisation comprising forty-five European countries, which promotes standards of democracy and human rights within member states. Distinct from the European Union.
Cross Matching	A test for compatibility between donor and recipient blood, carried out prior to transfusion to avoid reactions between the donor's red blood cells and antibodies in the recipient's plasma, or the reverse.
Elective Surgery	Surgery which is not immediately needed and can be scheduled for a later date.
Erythropoietin (EPO)	A hormone produced by the kidneys that stimulates the production of red blood cells by bone marrow.
EU Directive	Binding agreement on all European Union member states which must be legislated for by individual governments.
Haematology	The study of blood and blood forming tissues.
Haematologist	A doctor who specialises in the treatment of blood diseases.
Haemostasis	The arrest of bleeding.
Health Department Letters (HDL)	Formal communications from the Scottish Executive Health Department to NHSScotland.
Health Technology Assessment (HTA)	Policy analysis which studies the medical, social, ethical and economic implications of a health technology.
Hospital Blood Bank	A hospital unit which stores, tests and distributes blood and blood components for exclusive use within hospital facilities.
Term	Definition

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MEL	Management Executive Letter (now known as Health Department Letters - HDL). See HDL.
National Institute for Clinical Excellence (NICE)	Independent organisation responsible for providing national guidance on treatments and care for those using the NHS in England and Wales.
Near Patient Testing	Test procedures which can be carried out in close proximity to the patient and the results reported immediately.
Perioperative	Period immediately before, during and after a surgical procedure.
Plasma	A cellular fluid in which blood cells are suspended.
Platelets	Cells found in blood which are important for coagulation and repair of blood vessels.
Red Cells	Oxygen carrying blood cells.
Scottish Intercollegiate Guidelines Network (SIGN)	Umbrella organisation of healthcare professional bodies. SIGN develops clinical guidelines for effective practice.
Scottish National Blood Transfusion Service (SNBTS)	Responsible for the collection, storage and distribution of blood and blood products for transfusion patients in Scotland.
Serious Hazards of Transfusion (SHOT)	Scheme to collect information on adverse transfusion incidents
Transfusion	The introduction of whole blood or blood components directly into the blood stream.
Term	Definition
Whole Blood	Blood that has not been separated into its components

Appendix 1

Steering Group Members

Mrs Helen Cadden	Lay Representative
Mr Paul Dale	Chief Biomedical Scientist, Lothian University Hospitals Division
Mrs Sandra Falconer	Policy Manager, Scottish Executive Health Department
Dr Rachel Green	Clinical Director, West of Scotland BTS
Dr Lynn Manson	Consultant Haematologist, SE of Scotland BTS
Dr Brian McClelland	Consultant, SNBTS
Ms Rosanna Ralston	Clinical Project Co-ordinator, Ayrshire Central Maternity Hospital
Miss Linda Sinclair	Practice Development Facilitator, Practice Research Development and Education Department
Mr Henry Smith	Head of Technical Services, Haematology Services
Ms Wilma Spencer	Senior Midwife, Practice Development, Simpson Centre for Reproductive Services
Mr Ian Stephenson	Pathology Manager, BUPA Murrayfield Hospital
Dr Campbell Tait	Consultant Haematologist, NHS Greater Glasgow North Division
Dr Angela Thomas	Consultant Haematologist, Royal Hospital for Sick Children

From NHS QIS:

Ms Joyce Craig	Senior Health Economist
Ms Hilary Davison	Team Manager, Standards Development
Miss Gillian May	Project Administrator
Mr Neill O'Shaughnessy	Senior Project Officer
Mr Darren Ross	Project Officer
Ms Alison Stout	Health Services Researcher
Ms Jan Warner	Director of Performance Assessment and Practice Development

Appendix 2 NHS QIS Product List

Product Name	Audits
Description	Individual audit projects or co-ordinated programmes of work with a national focus addressing specific topic areas and funded by NHS QIS. Final reports peer reviewed and published. Previously overseen by Clinical Effectiveness Programmes Sub-group (CEPS) of CRAG. (Project-based planned work)
Product Name	Best Practice Statements
Description	Individual reports providing guidance on best and achievable practice on specific topics identified by nurses, midwives and allied health professionals as being priorities. Blend of evidence and professional consensus compiled by multi-disciplinary working groups of relevant experts. Disseminated widely within NHSScotland. (Project-based planned work)
Product Name	Clinical Governance/ Effectiveness Support
Description	Widely varied work supporting clinical governance activities in NHSScotland including networks, training, conferences and workshops, expert groups, surveys and feedback, provision of advice and guidance, educational activities, library and information services. (Non-project-based, responds to demand)
Product Name	Clinical Outcome Indicators
Description	Annual report of outcome indicators on a range of health topics varying from year to year, showing trends over time and geographical variation at health board and/or Trust level. Overseen by Clinical Outcomes Working Group; data analysis by ISD using national data. All topics are published at the same time.
Product Name	Comments on NICE Guidance
Description	An email alert about issuing the NICE Guidance to Scotland and highlighting any important contextual differences affecting its use in Scotland such as: principles and values of NHSScotland, epidemiology, structure and provision of services in Scotland and other implications, e.g. rural issues, predicted update, existing advice from SMC. (Project based, planned work)
Product Name	Evidence Notes

NHS QIS: Report of the Steering Group on the Safe, Effective and Efficient Use of Blood Components and their Alternatives

Description A one page note which highlights key issues for health service planners and practitioners and directs them to robust sources of evidence (or lack of evidence) on a particular topic or clinical area which is believed important for NHSScotland. (Non-project-based, responds to demand)

Product Name Frameworks
Description (Non-project-based, responds to demand)

Product Name Health Technology Assessments (full)
Description Advice on the clinical effectiveness, cost effectiveness, patient issues and organisational issues associated with using a health technology in NHSScotland. (Project-based planned work)

Product Name Health Technology Assessments (short)
Description Advice on the clinical and cost effectiveness of a health technology in NHSScotland. (Non-project-based, responds to demand)

Product Name Managed Clinical Networks
Description Advice and support in the development of each managed clinical network's Quality Assurance Framework, in accordance with NHS QIS guidance manual, followed by formal endorsement of the QA Framework which is valid for 3 years. During the 3 year endorsement period annual reports are reviewed, and at its conclusion the revised framework is evaluated. (Non-project-based, responds to demand)

Product Name Quality Indicators and Local Reviews
Description Quality Indicators for Learning and Physical Disability services, mental health and services for the frail and elderly. Reviews are carried out on an area-wide basis every 2-4 years and findings are published. Visits are routinely followed up by an action plan or revisit if required. (Project-based planned work)

Product Name SIGN Guidelines

NHS QIS: Report of the Steering Group on the Safe, Effective and Efficient Use of Blood Components and their Alternatives

Description A practical guideline of recommendations based on evaluation and synthesis of available evidence derived from a systematic literature review. The draft is consulted on publicly and within the Service, after which the guideline is distributed for implementation at local level. (Project based planned work)
NHS QIS funds and approves the SIGN programme of work, but guideline content is the responsibility of the SIGN Council.

Product Name SMC Product Assessments

Description Advice to NHS Boards and their Area Drug and Therapeutics Committees (ADTCs) across Scotland about the status of all newly licensed medicines, all new formulations of existing medicines and any major new indications for established products. This advice will be made available as soon as practical after the launch of the product involved. (Non-project-based, responds to demand)
NHS QIS facilitates the work of the Scottish Medicines Consortium, but the assessments are the responsibility of the SMC Chair and the Consortium.

Product Name Standards and Reviews

Description The development of draft standards which are finalised after extensive public consultation (the Standards phase). Following a period during which the standards are assimilated into NHSScotland working practice, all providers of the relevant service are assessed against the standards. Individual reports and a national overview reporting the assessment of performance against the standards are published (the Review phase).
(Project-based planned work)

Appendix 3 Presentation Topics

1. **Topic:** Standards for Blood Transfusion and Blood Management: Why?
Presenter: Dr Brian McClelland, Consultant, SNBTS
Date: 28 April 2004
2. **Topic:** NHS Quality Improvement Scotland
Presenter: Hilary Davison, Team Manager, Standards Development, NHS QIS
Date: 28 April 2004
3. **Topic:** Audit Scotland Hospital Blood Banks Report
Presenter: Dr Steve Engleman, Health Economist
Date: 28 May 2004
4. **Topic:** Supporting Best Transfusion Practice Across Scotland
Presenter: Mr Fraser Fergusson, Programme Director, BBTP
Date: 30 June 2004